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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,738	03/06/2006	Joshua E. Medow	09820283/P03355US	8705
60961 7590 04/14/2010 Intellectual Property Dept./Dewitt Ross & Stevens Wisconsin Alumni Research Foundation 2 East Mifflin Street, Suite #600 Madison, WI 53703-2865				
EXAMINER				
WIEST, PHILIP R				
ART UNIT		PAPER NUMBER		
3761				
NOTIFICATION DATE		DELIVERY MODE		
04/14/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket-ip@dewittross.com

Office Action Summary

Application No.

10/570,738

Applicant(s)

MEDOW ET AL.

Examiner

Philip R. Wiest

Art Unit

3761

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-16, 18-21, 58, 60-75 and 78-83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-16, 18-21, 58, 60-75 and 78-83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Final Drawing Review (PTO-849)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/19/10 has been entered.

Response to Amendment

In the reply filed 3/23/10, applicant added claims 78-83. Claims 1-6, 8-16, 18-21, 58, 60-75, and 78-83 are currently pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 states that the valve comprises a mask that is at least partially affixed to the piston, the mask having a cutout defined thereon. This contradicts Claim 1, which states that the piston comprises a cutout defined therein.

Further, if applicant rewrites this limitation as an independent claim, it will be withdrawn from consideration as being drawn to a distinct species of the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5, 6, 8-15, 17-21, 58, 60, 62, and 64-71, and 78-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubenstein et al. (US 7,025,742)

With respect to Claim 1, 5, 6, 8-11, and 78-83, Rubenstein et al. (hereafter 'Rubenstein') discloses a fluid shunt for regulating the flow of cerebrospinal fluid ("CSF"), said shunt comprising an inlet port 184, an outlet port 186, a fluid passageway between said inlet and outlet, and a valve 194 situated between the inlet and outlet. The valve defines a drain port between an upstream side and a downstream side of the fluid passageway. The valve comprises a mask having a cutout thereon that is alignable with the drain port. The device further comprises a piston 196 having a piston face defined on the upstream side of the passageway and being displaceable to actuate the valve. The fluid bearing on the piston face will actuate the valve and allow fluid communication between the inlet and outlet ports. When the piston is activated by the presence of a threshold pressure, the cutout will be moved vertically so as to selectively allow fluid flow through the drain port (see Figure 17). The piston is displaceable along

a vertical piston travel axis, and fluid flowing through the cutout valve between the upstream and downstream sides flows substantially perpendicular to said axis. When a sufficient pressure differential across the diaphragm is present, the diaphragm will displace the piston along the travel axis and open the valve. Further, because the valve is initially in the closed position, downstream pressure is substantially prevented from affecting the position of the piston (see Figure 16). Therefore, the position of the piston is independent of the pressure in the downstream side of the fluid passage.

1. Rubenstein teaches the device substantially as claimed, but does not specifically teach that the cutout is defined on the sidewall of the *piston*.
2. However, it has been held that the mere rearrangement of parts does not constitute a patentable improvement in the art when said rearrangement does not provide a non-obvious difference in functionality (MPEP § 2144.04). In this case, Rubenstein teaches a piston that is integral with a valve member, the valve member serving to *selectively block* fluid flow from the inlet to the outlet. The valve member 194 further comprises a cutout for allowing fluid to pass when the piston is disposed at a specific height (i.e. when a specific amount of pressure is present within the chamber). However, it is the examiner's position that the specific vertical location of the cutout is irrelevant, *so long as it corresponds with the vertical position of the piston such that it selectively opens and closes in response to pressure differences*. Merely repositioning of the cutout from the wall from the sidewall of the valve to the sidewall of the piston would have been an obvious rearrangement of parts to one of ordinary skill in the art at

the time of invention, because doing so would provide a pressure-responsive cutout valve that responds only to fluid pressure in the upstream portion of the device.

3. With respect to Claims 18, 20, 21, and 68-70, the device is designed to drain CSF from the cranium to a resorption site, such that the peritoneum.

4. With respect to Claim 19 and 71, the outlet portion 4 has an extended flexible catheter 5 extending therefrom.

Claims 2, 12-15, 58, 60, 62, and 64-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubenstein in view of Drevet et al. (US 5,643,195). Rubenstein reasonably suggests the device substantially as claimed, and further teaches that the piston is biased by a biasing member (spring 200). Rubenstein, however, does not specifically teach that the biasing member is a deformable diaphragm.

Drevet teaches a CSF shunt comprising a flow control member having an inlet port, an outlet port, a fluid passageway between said inlet and outlet, and a valve 14 situated between the inlet and outlet. The valve defines a drain port between an upstream side and a downstream side (6 and 13) of the fluid passageway. A piston is configured to selectively position the valve based on fluid pressure (see Abstract). The fluid bearing on the piston face will actuate the valve and allow fluid communication between the inlet and outlet ports. Specifically, a portion of the piston face is defined by

a deformable diaphragm 9 that includes a fluid side 7 bounded by the upstream side 7 of the fluid passageway, and an opposite side isolated from the fluid passage. The deformable diaphragm is connected to a spring 17 such that the diaphragm and spring provide a biasing force to maintain the valve in a closed state unless a sufficient pressure differential is provided. When fluid pressure in the first chamber builds, the fluid will press against the diaphragm, thereby urging the piston downward. Once the fluid pressure against the piston reaches a threshold level, it will overcome a biasing force provided by the biasing member, thereby displacing the valve and allowing fluid to flow. Once fluid pressure drops back below the threshold level, the biasing member will urge the piston upward, thereby closing the valve. Further, Drevet teaches that the pressure of the spring 17 is capable of being adjusted by means of a screw 18 (see Figure 1). This type of piston biasing system is well known in the art because it allows for precise pressure-based control over the position of the valve. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the flow control system of Rubenstein with Drevet's diaphragm-based piston biasing system in order to provide a well-known, alternate means for controlling fluid flow through the valve in response to upstream fluid pressure.

5. Claims 3, 4, 16, 61, and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubenstein in view of Drevet, and further in view of Drake et al. (US

5,192,265). Rubenstein and Drevet reasonably suggest a flow-regulating CSF shunt substantially as claimed (see rejection above), but do not specifically disclose that the diaphragm comprises a fluid side in contact with the upstream chamber and a gas side, opposite the fluid side, bounded by a regulatable gas chamber. Drake discloses an adjustable CSF shunt comprising a fluid passageway 5 surrounded by a pair of flexible walls (i.e. diaphragms). A gas chamber 9 is disposed on the opposite side of the flexible sheets from the fluid passageway, such that pressure is applied to the diaphragms to form a valve (Figure 1). When a low pressure differential exists between the inlet and the outlet, the valve is closed. When a pressure differential between the inlet port 7 and outlet port 8 is present, however, the diaphragms will deform, allowing fluid to pass through the fluid passageway. Furthermore, Drake discloses that the gas pressure in the gas chamber 9 may be manually adjusted by moving a ball 14 through the gas pressure control means 10 (Column 3, Lines 34-44). The use of a gas source therefore allows a pressure to be applied to the opposite side of the diaphragm, thus eliminating the need for a spring member to apply pressure to the diaphragm. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the flow control device of Rubenstein and Drevet with the use of a gas source to apply pressure to the opposite side of the diaphragm in order to provide a well known, alternate means for controlling the pressure differential between the inlet and outlet of a CSF shunt.

6. Claims 72-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubenstein in view of Drevet, and further in view of Zinger et al. (US 6,379,340). Rubenstein and Drevet reasonably suggest the device substantially as claimed. Specifically, Rubenstein and Drevet both teach the use of a piston that moves in response to a pressure differential, and Rubenstein teaches the use of a cutout valve that extends perpendicular to the piston travel axis. Rubenstein and Drevet, however, do not specifically teach that the cutout of the piston moves along a curved path between the first and second positions. Zinger et al. (hereafter Zinger) teaches a flow control device comprising a piston having a cutout 25 therein that extends along the wall of the piston, thereby defining a drain port (see Figure 4). The device may be rotated in order to establish fluid flow between the inlet 14 and the outlet 16 of the flow path. The rotational valve of Zinger therefore performs the same function as the axially-displaceable piston of Rubenstein, except that it is displaced rotationally instead of axially. However, it has been held that substituting equivalents that are known for the same purpose does not constitute a patentable improvement in the art (see MPEP § 2144.06). Rotationally-displaced fluid valves having cutouts extending therethrough, such as that of Zinger, are commonly used in the art (see also Wilson et al. – US 5,540,668). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the fluid control device of Rubenstein and Drevet with the rotationally-displaceable valve actuator of Zinger in order to provide a well-known, equivalent means for controlling fluid flow between an inlet and an outlet.

Response to Arguments

Applicant's arguments have been fully considered and are persuasive.

Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly considered prior art (Rubenstein).

Further, regarding the use of the Zinger patent, applicant presents the following arguments:

1. Given the teachings of Zinger, one of ordinary skill in the art would not have had the foresight to derive the claimed invention from other axially-displacing valves in the art.

This argument has not been found persuasive. It is the examiner's opinion that cutout valves that displace axially and rotationally are both well-known means for providing flow control. In this case, it would have been within the scope of one of ordinary skill in the art at the time of invention to modify Rubenstein's device to displace rotationally. A rotating cutout valve does not provide any non-obvious advantages over one that displaces axially.

2. Zinger is not an art-recognized equivalent to other implantable piston-controlled valves.

This argument has not been found persuasive because Rubenstein and Zinger both teach the use of cutouts to control fluid flow. The examiner takes the position that it is well known in the art that rotationally and axially displaceable cutout valves are equivalents in the art. Therefore, it would have been within the scope of one of ordinary

skill in the art at the time of invention to modify Rubenstein's device to displace rotationally.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip R. Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Philip R Wiest/
Examiner, Art Unit 3761
/Leslie R. Deak/
Primary Examiner, Art Unit 3761
11 April 2010